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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/312,485	05/17/1999	PATRICE DEBREGEAS	065691/0163	2681

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/312,485

Applicant(s)

DEBREGEAS ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. Amendment filed on October 03, 2002 has been entered. Claims 1-21 are pending.

Applicant's arguments filed October 03, 2002 have been fully considered but they are not persuasive for the reasons set forth below.

#### ***Response to Arguments***

2. Claims 1-2, 4-5, 9-13, 16-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Cingotti US Patent 5,427,800 (IDS, filed on 2/3/99, Paper No.6).

Applicant first argues that Cingotti's microgranules are obtained by different methods and are porous in nature. In response, Examiner states that the instant claims are neither directed to such limitations, nor exclude such limitations; therefore, Applicant's arguments are not commensurate with the scope of the claims.

Further, to argue such unclaimed limitation and without setting forth any evidence, Applicant relies on the assumption that "it is well known that neutral pellets are dense and unified and possess a homogenous structure." In response, Examiner again states that the instant claims are not directed to neutral pellets. Assuming that neutral pellets and neutral core are meant to refer to the same entity, during prosecution of a patent application, they are interpreted given their broadest reasonable interpretation in the art.

Accordingly, "neutral" is viewed to mean free of charge and "core" is viewed to mean the innermost layer (see definitions on Webster II, Riverside Dictionary). Thus, the terminology is viewed to be an innermost layer that is free of charge. Moreover, a

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neutral core in the art can comprise various divergent moieties including liposomal vesicles or micelles (see US Patent 5,104,661 at col 6, lines 46-51). Such interpretation of the term in the art indicates that neutral cores in the art are not defined as a dense and unified homogenous structure. Therefore, Applicant's arguments that neutral pellets or cores are known to be dense and unified is not commensurate with the scope of the pending claims and further are inaccurate.

Applicant further argues that Cingotti's granules must have a strong adsorption capacity or are prepared without the intermediary steps that produce homogenous neutral core. Again, such arguments are not commensurate with the scope of the pending claims as they are not excluded from the instant claims. The instant claims are directed to granules containing at least one plant substance comprising a neutral core having a particle size of between 200 and 1600 m coated with a layer of plant substance and an excipient.

Cingatti discloses such limitations by disclosing coated microgranules having dimensions between 0.1-1 millimeter (100-1000microns) (example 1, example 4, col 5, lines 3-5). Cingatti coated his microgranules with a plant extract or tincture (*example 1-2*). Cingatti specifically discloses silica crystalline powder having 210-500 microns coated with alcoholic tincture of passiflora (*col 3 lines 40-65*). Cingatti also teaches the use of excipient on the microgranules of ose-compounds (see col 6, lines 6-18). Further, the process steps of Cingatti include all the process steps of the instant claims. Thus, claims stand rejected for the reasons of record.

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3. Claims 3, 6-8, 14-15, 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cingotti US Patent 5,427,800 (IDS filed on 2/3/99, Paper No. 6) and Menzi et al US Patent 6,056,949 in view of Breitenbach et al US Patent 6,120,802 (PTO-892 filed on 10/11/00).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In the instant case, the combined teachings of the references render the instant claims obvious as of record.

Cingotti fails to teach the use of a delaying or flavoring agent. Menzi teaches the use of flavorant or odorants in his coating emulsion that can contain various modified cellulose (encompassing hydroxymethylcellulose), plant extract, and/or synthetic material such as polyvinyl pyrrolidone(PVP) (*col 6, lines 50-56; col 2, lines 46-48*).

Menzi does not use methacrylic acid, plasticizer or binders in their formulations.

Breitenbach teaches the use of various conventional additives including plasticizer, binders such as hydroxypropylcellulose, PVP, acrylic acid copolymers to formulate their multi layer compositions, (*col 9 lines 1-37*). Therefore, all components of the instant claims are taught in the art and are combinable as of record.

### ***Conclusion***

4. **No claims are allowed. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200

ss

December 23, 2002